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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,954	03/27/2001	Christopher J.R. Paszty	A-676B	9125

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,954	PASZTY ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,11,47-51,61 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,11,47-51,61 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/9/2004 has been entered.

Based upon applicants arguments in the response filed 1/9/2004, taken in combination with the Nakabayashi paper cited by applicants (JCI 109:1445, 2002) The utility rejection under 35 U.S.C. §101 is withdrawn. The rejection for lack of enablement is withdrawn to the extent that it applies to the nucleotide sequence of SEQ ID NO: 2 of a nucleic acid encoding the protein of SEQ ID NO: 1. However, the enablement rejection is maintained as it applies to the scope of the claims, as set forth below.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10, 11, 47-51, 61 and 65 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO: 2 or that encodes SEQ ID NO: 1, does not reasonably provide enablement for the breadth of the claims, which encompass numerous fragments, derivatives, etc. of such. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of this invention is the discovery of two new glycoprotein hormone subunits, designated α2 and β10 by applicants, and α2 and β5 by Nakabayashi et al. The state of the art is that the glycoprotein hormone family was previously known to comprise four members, LH, FSH, hCG, and TSH, which are heterodimeric proteins that share a common α subunit. It was also known in the art, as summarized by Nakabayashi et al., that the effect of structural alterations in the glycoprotein hormones is not predictable (see page 1451, second column). Further, Nakabayashi et al., which is not prior art, but is art subsequent to the filing date of this application, disclose that "a heterodimer consisting of the known α and new β5 subunits did not activate the TSH receptor, and the A2/CGβ heterodimer did not activate the LH receptor." Therefore, Nakabayashi et al. teach that the newly identified glycoprotein hormone differs substantively from the previously known four species, in that its subunits may *not* be interchanged with those of the other known family members. Thus, the art evidences a lack of predictability in making alterations to glycoprotein hormones in general, an α2/β10 in particular.

The claims are extremely broad. The specification discloses a single species of protein, having a particular amino acid sequence. However, the claims encompass nucleic acids that hybridize under non-specified conditions to the disclosed sequence or to degenerate variants of said sequence, nucleic acids encoding proteins having as little as 70% identity to the protein of SEQ ID NO: 1 and retain "an activity of the human α2/β10 heterodimer" allelic and splice variants, fragments of any of the above nucleic acids without regard to any function whatsoever, and nucleic acids encoding proteins with unlimited substitutions, deletions, insertions,

truncations. The specification provides no working examples other than the single disclosed protein sequence for each of the two subunits, and provides merely general, non-specific guidance as to alterations that might be made, with no specific direction as applied to the particularly disclosed proteins. Further, there is not disclosure of any splice or allelic variants.

Accordingly, the Examiner concludes that while the specification enables one to make and use the nucleotide sequence of SEQ ID NO: 2 of that which encodes SEQ ID NO: 1, it would require undue experimentation to make and use the invention in a manner commensurate in scope with the claims.

Regarding guidance in the specification as to "an activity of human α2/β10 heterodimer", the specification provides guidance to such by way of analogy to TSH. For Example, at page 10 the specification states: In addition, diagnostic tests for measuring TSH levels in the blood are commonly used for determining the functional status of the thyroid gland when thyroid gland disorder is suspected. It is likely that human α2/β10 will have similar clinical utilities as TSH and will be useful for the treatment and diagnosis of thyroid gland related diseases and disorders. While this statement was not, in the absence of any further evidence persuasive of utility or enablement, the subsequent art, in the form of Nakabayashi et al. , has shown the statement to be at least partially true; the human α2/β1 binds with high affinity to TSH receptors, and therefore has diagnostic utility for thyroid imaging, at least. However, no activity was specifically disclosed in the specification as filed, and the protein surely has other activities than binding TSH receptor. As the specification does not breath life and meaning into the phrase "an activity of human α2/β10 heterodimer", such must be interpreted in the broadest reasonable sense as reading on any possible activity of the α2/β10 heterodimer. As the specification did not disclose any specific activity of the heterodimer, it is concluded that it would require undue experimentation to discover the various activities of such, and then test species to determine whether they fall within the metes and bounds of the claims.

Claims 1-8, 10, 11, 47-51, 61 and 65 remain rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the first office action on the merits, mailed 11/21/2002.

Applicants arguments, filed 1/9/2004, have been fully considered but are not deemed persuasive. Applicants argue that two species are disclosed, mouse and human. The point is well taken, and the Examiner finds adequate written description of both mouse and human β10. However, it remains that the disclosure of those two species is not commensurate in scope with the breadth of the claims, which is discussed in the above rejection under 35 U.S.C. §112, first paragraph. Given the unpredictability in the art, the Examiner concludes that merely disclosing that a certain type of variation is envisioned (70% identity, allelic variants, etc.) is not a description of such. Further, comparison to the previously known glycoprotein hormone subunits is not probative, in view of Nakabayashi et al.'s disclosure that α2 and β10 do not function in concert with the previously known subunits.

At page 10, applicants argue that TSH-like activity, "and other significant activities" are fully described in the specification as originally filed. This argument has been fully considered but is not deemed persuasive because while Nakabayashi et al. have substantiated that α2/β10 binds to TSH receptors, it remains unpredictable what, and if any which disorders are related to α2/β10. Nakabayashi et al. teach that the physiological role of α2/β10 is expected *not* to be the same as TSH, based upon expression patterns. Accordingly, any allusion to disorders that may be treated using such is a mere invitation to experiment to find such disorders.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10, 11, 47-51, 61 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims that recite "moderately" or "highly" stringent conditions, such as claims 1-3, remain indefinite because there is no limiting definition of such in the specification, and the metes and bounds of that which will hybridize are dependent upon the conditions under which

the hybridization is performed. The discussion of such at pages 31-33 of the specification is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite. Applicants citation of textbooks and the knowledge of one skilled in the art has been fully considered but not deemed persuasive as the terms are relative terms with no well-defined limits in the art, and therefore is not persuasive for reasons cited in the original rejection and reproduced herein. Applicants argument, which reiterates the definitions found in the specification, is not persuasive, as it remains that the terms are relative, and the definitions are non-limiting. Note that Sambrook et al. define conditions in part by what the desired outcome is.

Claim 2 remains further indefinite at part (d) of the claim, as the nature of the 'fragment of at least 16 nucleotides thereof' is not clear. This also applies to other claims, for example claim 3, part (f). Applicants have amended the claims in an effort to overcome this rejection. However, the insertion of the word "thereof" is not remedial, as the antecedent basis for the term is not clear, as it might refer back to any of a number of things. Further, a nucleotide sequence cannot be a fragment of itself; part (d) might intend (in part) ' a nucleotide sequence of SEQ ID NO: 2 comprising a fragment of at least about 16 nucleotides of SEQ ID NO: 2'. Such is nonsensical. Claim 3 is similarly indefinite at part (f).

Claim 3 remains further indefinite for failing to adequately point out that which applicant sees as the invention. There is no upper limit to the number of substitutions, insertions, deletions, or truncations, such that there is no requirement for any structural similarity to the disclosed nucleic acids. Applicants traversal that the specification provides 'ample disclosure to allow one skilled in the art to determine appropriate substitutions" etc. has been fully considered but is not deemed persuasive. This is not an enablement rejection, but rather a rejection under 35 U.S.C. § 112, second paragraph on the basis that the metes and bounds of the claims cannot be determined. As claim 3 has no limits on the number of changes, one of ordinary skill in the art would not be able to determine whether a given protein did or did not fall within the metes and bounds of the claim, and the claim fails to point out with particularity that which is the disclosed invention. If applicants argument is intended to indicate that the claim is intended to cover all functional equivalents of SEQ ID NO: 1, then such would support the basis of the rejection under 35 U.S.C. §112, first paragraph, as the claim as thus interpreted is a single means claim.

Claim 8 also remains further indefinite for failing to adequately point out that which applicant sees as the invention: while applicants have deleted reference to β10 from the claim, the result is that the claim now reads on production of *any* protein made by the cell, regardless of whether that protein is or is not encoded by the claimed nucleic acids. For example, the claim encompasses production of DNA polymerase, which is made by all cells. As such, the claim is indefinite for failing to adequately point out that which applicant sees as the invention.

Claim 61 remains indefinite as the metes and bounds of "human β10 polypeptide" are not clear. Applicants traversal of this rejection has been fully considered but is not deemed persuasive. The cited portion of the specification does not use the term "human β10 polypeptide". Such might refer either to a β10 polypeptide isolated from a human, or alternatively to any polypeptide with similar activity to human β10, for example. As the specification does not breath life and meaning into the term, the claim is indefinite. Applicants citations of the specification at page 13 of the response filed 1/9/2004 have been fully considered but are not deemed persuasive. While the specification provides an example of a single human β10 polypeptide, it remains that there is no definition of what is encompassed by the term "β10" so as to breathe life and meaning into the claims. Without such, the scope of the claim cannot be determined. The mere recitation of a name, i.e. β10, to describe the claimed invention is not sufficient to satisfy the statute's requirement of adequately describing and setting forth the inventive concept. For example, there is an unrelated protein, a chemokine, also designated β10, see U.S. Patent Number 6,673,344. In order to avoid possible confusion over proteins with the same or similar names that may be found to have patentably different structure and/or utility, proteins claimed by a particular name should be further distinguished in the claims by conventional protein characterization according to known parameters, e.g. such as by molecular weight, pI, amino acid sequence information, whether the protein is a monomer or multimeric, function(s) and/or activity, and/or other finger-printing techniques such as IR, NMR, or UV spectroscopy data and/or other known properties which would serve to distinguish the claimed protein from other proteins. In addition, in consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel

electrophoresis, gel filtration or some other method, and whether reducing or non-reducing (native) conditions were used.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10, 11, and 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Mosselman et al., US 2003/0059877 A1, published 3/27/2003. Applicant is advised that in making this rejection, priority for the instant application is granted only to the filing date of the instant application, 3/27/2001, on the basis that the disclosure in the parent application, 09/723970 did not comply with the requirements of 35 U.S.C. §101 and §112, first paragraph. The Mosselman et al. application is the U.S. Stage of a PCT with an effective filing date of 1/17/2001.

Mosselman et al. disclose a nucleic acid, SEQ ID NO: 1, that is 100% to the entirety of SEQ ID NO: 2 of the instant application, at Mosselman's nucleotides 101-490. Mosselman's SEQ ID NO: 2 (encoded by SEQ ID NO: 1) is 100% identical to applicant's SEQ ID NO: 1, but lacks the final two amino acids. Vectors, host cells and expression of protein are also disclosed, see claims. Viral vectors are disclosed at paragraph [0033]. Fusion proteins are disclosed at paragraph [0040].

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mosselman as applied to claims 1-8, 10, 11, and 47-50 above, and further in view of Capon et al., U.S. Patent Number 5,116,964.

The teachings of Mosselman et al. are summarized above. Mosselman teaches the use of the protein, which is identified as being a new member of the glycoprotein hormone family, in pharmaceutical compositions, but does not teach or suggest Ig fusions comprising the protein.

Capon teaches fusion proteins comprising immunoglobulin polypeptides fused to "ligand binding partners", which are defined as including hormones and growth factors (see column 2, lines 14-19). At column 4, lines 38-43, Capon states that the immunoglobulin (Ig) fusions of the invention "serve to prolong the in vivo plasma half-life of the ligand binding partner..." and "facilitate its purification by protein A". Also taught are recombinant materials for making such a fusion protein, vectors and expression; see columns 15-16. Preferred embodiments include sequences including the hinge regions of IgG-1, -2, -3 or -4, IgA, IgE, IgD and IgM, see column 14, lines 40-45 (the first domain of the constant region can be omitted). The preferred species of Ig was human, see claims 8-9. Capon states that the DNA sequences for the Ig chains were well known in the art at the time the invention was made, see column 15 beginning at line 40.

Accordingly, it would have been obvious to modify the protein taught by Mosselman et al. to comprise sequences from and IgG constant domain, in view of Capon's teaching that such is useful to facilitate purification and serum half-life of proteins. One would have been

motivated to do so by Mosselman's teaching that the protein can be purified and used as a pharmaceutical. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the prior art.

Claims 1-5, 7 and 11 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103(a) as being obvious over G.G. Mahairas et al., Locus AQ495547 disclosed 4/28/99 for reasons of record.

Applicants traversal has been fully considered but is not deemed persuasive. To the extent that applicants arguments are duplicative of previous arguments, they remain non-persuasive for reasons of record. Applicants now allege, at the bottom of page 14, that cysteines C12, C36 an dC40 "are critical for the activity of the molecule, are encoded by exon 1, and are not present in the portion of the truncated β10 polypeptide encoded by the Mahairas sequence." This argument has been fully considered but is not deemed persuasive because (a) applicants have not pointed out basis in the specification as originally filed for the assertion that the cysteines are essential for activity, (b) the claims do not require any *specific* activity but rather, require only *an* activity, which as previously stated, is interpreted to include antibody binding and (c) applicants assertion that the polypeptide of Mahairas would not be able to dimerize with α2 is not supported by fact or evidence. Note that claim 1 has an activity limitation only for part (c) of the claim, which does not apply to parts (a) and (b), as the claim is written. At page 15, applicants argue that the sequence disclosed by Mahairas would not comprise an antibody binding epitope. This argument has been fully considered but is not deemed persuasive because the sequence of Mahairas encodes 66 amino acids *identical* to SEQ ID NO: 1. The person of ordinary skill in the art recognizes that fragments of protein much shorter than that are useful for making antibodies that will bind to a full length protein comprising such fragments. For example, Lerner, Advances in Immunology 36:1-44, Academic Press 1984, teaches exactly the opposite of what applicants assert; see for example pages 7-11, for a discussion of anti-peptide antibodies, page 27 which discusses results in which 16 out of 21 monoclonal antibodies raised against isolated peptides from influenza virus recognized both the peptide they were raised

against and the whole virus, and page 33, which states that "sufficient structural information is contained in peptides as small as 13 amino acids residues to induce protein reactive antibodies at a high frequency." Additionally, Lerner, Nature 299:592, 1982, teaches that protein fragments are useful as antigens for the production of antibodies. Lerner teaches that the use of fragments for the production of antibodies allows production of antibodies reactive to a wider variety of antigenic determinants than can be attained using whole protein (see, e.g. last sentence of paragraph bridging pages 593-594). At page 596, Lerner teaches "The minimum size of the peptide chosen is important and should be larger than six amino acids. We generally synthesize peptides of 15 amino acids. Considerably larger peptides have also proved useful but do not offer any advantage..." Accordingly, the person of ordinary skill in the art would expect the protein encoded by Mahairas' nucleic acid have common 'activity' to that of SEQ ID NO: 1 in that the majority of antibodies raised to the protein encoded by Mahairas' nucleic acid would be expected to bind to the protein of SEQ ID NO: 1. Applicants are reminded that the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the nucleic of the prior art does not possess the same material structural and functional characteristics of the claimed nucleic acid). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Merely casting aspersions without factual support is not sufficient to overcome the rejection.

Claims 6, 8, and 48-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mahairas et al., locus AQ495547, as cited above, in view of Sibson et al., WO94/01548.

Applicants once again traverse that there is no motivation to apply the teachings of Sibson to the DNA of Mahairas et al. This argument has been fully considered but is not deemed persuasive because as stated in the previous Office Action, Sibson et al. disclose that it is generally useful to place a desired cDNA sequence into an expression vector, host cell, and express the encoded protein, as well as to raise antibodies to proteins encoded by such cDNA's. See pages 8-13. Expression in eukaryotic cells, and the advantages thereof, are discussed at page 9, first paragraph. Fusion proteins are also taught, see page 11, lines 15-15 and 26-29. As Sibson is directed to DNAs such as that disclosed by Mahairas, which are obtained by cDNA

cloning, the person of ordinary skill in the art at the time the invention was made would have been motivated to use the DNA's disclosed by the primary reference to express and then isolate the encoded polypeptide using a heterologous promoter, to make a fusion protein of such, and to express such in eukaryotic cells, using a viral vector, all as taught by Sibson et al. in view of Sibson et al.'s suggestion that it would be desirable to do so, as cited above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner